

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER **064150**

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. **CHEMIST'S REVIEW NO.** 4
2. **AADA#** 64-150
3. **NAME AND ADDRESS OF APPLICANT**
Eon Labs Manufacturing, Inc.
227-15 N. Conduit Avenue
Laurelton, NY 11413
4. **LEGAL BASIS FOR AADA SUBMISSION**
21 CFR §455.170a - The application is based on the reference drug Rifadin® manufactured by Merrell Dow Pharmaceuticals Inc. (NDA 50-420).
5. **SUPPLEMENT(s)**
N/A
6. **PROPRIETARY NAME**
N/A
7. **NONPROPRIETARY NAME**
Rifampin Capsules USP
8. **SUPPLEMENT(s) PROVIDE(s) FOR**
N/A
9. **AMENDMENTS AND OTHER DATES**
Firm:
Original Submission: 4/12/95
Amendment(bio): 12/14/95
Amendment (chemistry): 1/12/96
Amendment: 5/15/96
Amendment: 7/23/96

FDA:
Acceptance to File: 5/10/95
Bio Deficiency Letter: 10/31/95
Chemistry Deficiency Letter: 11/2/95
Chemistry Deficiency Letter: 3/19/96
Chemistry Deficiency Letter: 7/17/96
10. **PHARMACOLOGICAL CATEGORY**
Antibacterial
11. **HOW DISPENSED**
Rx

12. RELATED IND/NDA/DMFs

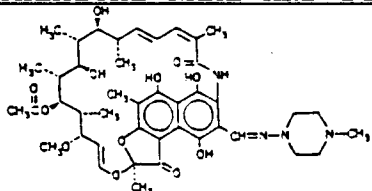
(b)4 - Confidential Business

13. DOSAGE FORM

Capsules

14. STRENGTH

300 mg

15. CHEMICAL NAME AND STRUCTURE

(1) Rifamycin, 3-[[(4-methyl-1-piperazinyl) imino]methyl]-;
(2) 5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,
20,22-heptamethyl-8-[N-(4-methyl-1-piperazinyl) formimidoyl]-
2,7-(epoxypentadeca[1,11,13]trienimino)naphtho[2,1-b]furan-
1,-11(2H)-dione 21-acetate.

$C_{43}H_{58}N_4O_{12}$

Molecular Weight: 822.95

16. RECORDS AND REPORTS

N/A

17. COMMENTS

All CMC issues have been resolved. Approval may be granted as soon as the FPL is submitted and found acceptable, and the bulk application is approved.

18. CONCLUSIONS/RECOMMENDATIONS

Approvable (bulk approval & FPL)

19. REVIEWER

Susan Rosencrance

/S/

DATE COMPLETED

8/13/96

ADDENDUM TO CHEMISTRY REVIEW #4

DATE: May 13, 1997
FROM: Susan Rosencrance
SUBJECT: Eon's Rifampin Capsules USP, 300 mg
TO: AADA 64-150

SUMMARY:

Chemistry has been acceptable since Chemistry Review #4 (completed 8/13/96). Approval could not be granted, however, until the bulk application [REDACTED] (b)4 [REDACTED] was approved and concerns with the labeling were resolved. Both of these pending issues have now been resolved and approval may be granted. For details concerning chemistry (release/stability specifications, etc.) see Chemistry Review #4.

REMARKS AND CONCLUSIONS:

Recommend approval

cc: AADA 64-150
Division File
Field Copy

Endorsements:

HFD-643/SRosencrance/5/13/97

HFD-643/JHarrison/5/13/97

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F/T by pah/5/15/97

[REDACTED] (b)4 - [REDACTED]

Confidential

see 5/13/97

5/15/97

APPROVAL